Single IRB

Marcella Oliver
IRB Reliance and Education Lead
NIH Single IRB Policy

The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.

This policy, which is consistent with 45 CFR Part 46.114, is intended to:

• Enhance/streamline IRB review process in multi-site research
• Eliminate duplicative IRB review
  – Reduce administrative burdens/inefficiencies
  – Maintain human subject protections
  – All IRB’s to concentrate on single site protocols
NIH Single IRB Policy cont.

Effective date: January 25, 2018

• Applies to: Domestic sites of NIH funded studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported by grants, cooperative agreements contracts or the NIH Intramural Research Program. It does not apply to Foreign Sites, career development (K), research training (T) or fellowship awards (F) and current awards.

• Exceptions: VA sites; international sites; sites involving tribal nations.
Roles and Responsibilities

Applicant/Offeror: Submit a plan describing the use of a Single IRB that will be the IRB of Record for all study sites. NIH acceptance will incorporate the plan into the terms and conditions of the award.

Awardees: Ensure authorization agreements are in place and ensure communication between the Single and participating sites.

Funding Institute or Center: Manage and oversee awards, communicate with awardee about the Single IRB compliance plan.
Roles and Responsibilities cont.

Overall PI and Lead Study Team

**Overall Study PI**
- Assumes leadership and responsible for conduct of the research
- Designates the Lead Study Team

**Lead Study Team**
- Submits materials to the Reviewing IRB for all sites, including study-wide and site-changes of protocol, continuing reviews, and reportable events
- Provides draft study materials to all site study teams, including proposed consent form template
- Provides IRB-approved study documents to all sites
- Communication Plan
Single IRB Plan

A Single IRB Plan should include the following elements:

- Name of the sIRB of record
- Indicate that: (1) All sites, including any added after award, agree to rely on the sIRB; (2) Sites will sign a reliance agreement that will include a communication plan; (3) Indicate who will maintain records of the reliance agreements
Single IRB Selection

- Identify the “lead” institution for the proposal and allow that institution “right of first refusal” to be the sIRB for all participating sites.

- NIH reserves the right to refuse the selected sIRB.
The selected sIRB is responsible for:

- Review of study and each site including any local context specific to the conduct of research.
- Mechanism for notifying each site of IRB review outcomes (i.e. initial review, modifications, continuing review, etc.).
- Maintaining Reliance Agreements for each site.
Relying Site Responsibilities

The selected relying site is responsible for:

• Providing local context information to the reviewing IRB.
• Not initiating any study procedures without External IRB approval specific to their site.
• Providing their local IRB with information regarding External IRB review.
• Ensuring the lead site PI is notified immediately of any reportable events that occur.
• Establishing a point of contact for their site.
Reliance Agreements

Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research.

A Reliance Agreement can be in many different forms, but some of the main agreements are:

- Memorandum of Understanding (MOU)
- Master Reliance Agreement (MRA).
SMART IRB Agreement
Supporting IRB reliance across the nation

Streamline IRB review and oversight of multisite studies and ensure robust protections for study participants.

For IRBs and Institutions

The SMART IRB Agreement:

• Enables reliance on a study-by-study basis
• Clearly defines roles and responsibilities
• Eliminates the need to sign reliance agreements for each study

Once you've joined SMART IRB, you may use the Agreement to support collaborations among Participating Institutions.

Learn more about how it works, or join now.

Review the Agreement

Review the agreement with institution officials and counsel.

- Join now
- Additional resources
- Agreement Version Guide
- We're here to help

Do not sign the sample Joiner Agreement.
SMART IRB cont.

Online Reliance System
Request, track, and document reliance arrangements

Investigators and institutions can use the Online Reliance System to request, track, and document reliance arrangements on a study-by-study basis.
- Simplifies the selection of a single IRB for multisite studies
- Manages communication between institutions and investigators
- Tracks the status of requests
- Clearly indicates what needs to be done next
- Documents reliance arrangements for each study
- NEW! Sites can be added to a reliance arrangement by amendment

Reliance Walkthrough Video
View by Topic
- Overview of the decision making process [1:53]
- Investigator submits a request [2:44]
- Identifying a proposed reviewing IRB [2:30]
- Recording Institution decisions [1:40]
- Issuing the determination [3:17]

Get Started
Use the Online Reliance System to enable reliance for your studies
Log in
Request Investigator Access
Institution Points of Contact (POCs): contact us to request access.

Attend a Webinar
Getting Started with SMART IRB & the Online Reliance System
Register Now Watch Previous Webinar
Implementing the SMART IRB Agreement (for Institutions and IRBs)
Register Now Watch Previous Webinar
Responsibilities of Relying Institutions
Register Now Watch Previous Webinar
SMART IRB Communication Model

Reviewing IRB

Lead Study Team

Lead Study Team operates similar to a coordinating center

Relying Institution IRB/HRPP

Relying Site Study Team
NIH Single IRB Implementation Plan (Phase 1)

- Pre-Consultation
- Dedicated Webpage
- Template Letters of Support
- SOP’s (HRP-092 External IRBs and HRP-093 NU IRB IRB of Record for Multi-Site Research)
- OSR/IRB Workflow
- Independent/Commercial IRB Questionnaire
IRB Institutional Review Board

NEW STUDIES
- Reliance Agreements
- Modifications
- Continuing Review / Closure
- Reportable New Information
- Compliance and Audits

Events
- Jul 19 - Chicago
  Reliance Agreements
  More information
- Aug 16 - Chicago
  Single IRB (NIH Policy)
  More information
- Sep _ - Chicago
  Media Relations / How

Information
- Need to Report A Concern?
- eIRB+ FAQs
- Research Participants
- AAHRPP Accreditation
- IRB Members
- CRC Overview

ATTENTION: eIRB+ Outage

IRB Closed for Independence Day Holiday
The IRB Office on both campuses will be closed Tuesday, July 4, to celebrate the Independence Day holiday. Read More »

IRB Closed for Memorial Day Holiday
The IRB Office on both campuses will be closed in observance of the Memorial Day holiday. Read More »
Single IRB Webpage

IRB Institutional Review Board

HOME > SINGLE IRB

Single IRB

Single IRB

The single IRB (sIRB) mandate is a set of complementary federal policies that require certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all of the institutions. The basis for the Single IRB Model is to allow multiple institutions that are conducting the same protocol to use a single IRB for review. The NU IRB has allowed the use of a Single IRB for over 5 years and is well versed to assist researchers in preparing for the new phase of required use.

There are two policies that require the use of a Single IRB (NIH Single IRB Policy and Common Rule Update).

Single IRB Policies

The NIH Policy, effective January 25, 2018
During pre-consultation, the NU IRB will evaluate on a case-by-case basis whether we are suited to serve as the sIRB for the proposed multi-site project.

- The risk level of the proposed research
- Number of sites
- The experience level of the NU PI
- Whether the NU site is the main funded site of the grant
- Conflict of Interest Assessment
# Pre-Consultation Intake Form

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<th>Record ID</th>
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<tbody>
<tr>
<td>Name</td>
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<tr>
<td>Email</td>
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<tr>
<td>PI Name (If different than above)</td>
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<tr>
<td>NIH Grant Type</td>
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<tr>
<td>NIH Proposal Due Date</td>
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<tr>
<td>Research Type</td>
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<tr>
<td>InfoEd ID Number</td>
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<tr>
<td>Type of IRB Request</td>
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**Response Options:**
1. NU IRB IRB of Record for Overall Study and External Sites  
2. NU IRB Ceding Review to an External IRB

**Study Synopsis (Please provide a brief description of the proposed research)**
eIRB+ Multi-Site Process

This project has at least one unsubmitted project site(s). Make sure you have completed all required information for each site, so the IRB Office can review them. You can access them in the Sites tab below.
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### Participating Sites

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>SmartForm</th>
<th>Institution</th>
<th>Principal Investigator</th>
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<tbody>
<tr>
<td>IRBSITE00000021</td>
<td>Columbia University IRB Participating Site for Multi-Site Test Study (MO)</td>
<td>[Edit]</td>
<td>Columbia University IRB</td>
<td>Marcella Oliver</td>
</tr>
</tbody>
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1 items
NIH Single IRB Implementation Plan (Phase 2) – Coming Soon!

- Single IRB Plan Template
- Updated Authorization Agreement Templates
- Fee Structure Analysis
- Process Analysis
- Investigator Workgroup
Contact Information

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QUESTIONS?